



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 19, 2014

Medela AG
Ms. Adrienne Lenz
Pathway Regulatory Consulting, LLC
W324 S3649 County Road E
Dousman, Wisconsin 53118

Re: K141926

Trade/Device Name: Invia Endure Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: November 14, 2014
Received: November 17, 2014

Dear Ms. Adrienne Lenz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Binita S. Ashar -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director

Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K141926

Device Name

Invia Endure Negative Pressure Wound Therapy System

Indications for Use (Describe)

The portable Medela Invia Endure Negative Pressure Wound Therapy (NPWT) system is indicated to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudates and infectious material. It is intended for the use in hospitals, clinics, Long Term Care (LTC) and Home Care (HC) settings on adult patients with chronic, acute, subacute, traumatic, dehiscent wounds, partial-thickness burns, ulcers (such as diabetic, neuropathic, pressure or venous insufficiency), flaps and grafts.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Medela AG
Invia Endure Negative Pressure Wound Therapy System

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: December 18, 2014

SUBMITTER:

Medela AG
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Pathway Regulatory Consulting, LLC
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Orlando Antunes
Vice President Regulatory Affairs
Medela AG

DEVICE:

TRADE NAME: Invia Endure

COMMON/USUAL NAME: Negative Pressure Wound Therapy System

CLASSIFICATION NAMES: 21 CFR 878.4780 Powered Suction Pump

PRODUCT CODE: OMP

PREDICATE DEVICE(S):

K080357 Medela Invia Wound Therapy

K113678 Medela Invia Motion Negative Pressure Wound Therapy System (Primary predicate)

Medela AG
Invia Endure Negative Pressure Wound Therapy System

DEVICE DESCRIPTION:

The Medela Invia Endure Negative Pressure Wound Therapy (NPWT) System is comprised of the Invia Endure NPWT Pump, canister/tubing set, power supply, carrying case, patient and user instructions, and Invia NPWT kits. The Invia Endure is also compatible with separately cleared Avance NPWT kits manufactured by Mölnlyke Healthcare (K122132).

The Invia Endure NPWT pump is a suction pump for Negative Pressure Wound Therapy with an optical and acoustic status display. Acoustic and optical signals are triggered for variances from the set values as well as for faults. The Invia Endure NPWT pump is intended for a single patient's entire therapy for continuous or intermittent operation. It has lifetime of at least three years.

The Invia Endure NPWT system is intended for use in a home or other health care facility by medical personnel or trained lay users adhering to the instructions for use. The user may not be hard of hearing or deaf and must have normal visual acuity. The Invia Endure NPWT pump is portable and can be operated independent of the electrical power supply via its rechargeable battery.

INTENDED USE:

The portable Medela Invia Endure Negative Pressure Wound Therapy (NPWT) system is indicated to create an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudates and infectious material. It is intended for the use in hospitals, clinics, Long Term Care (LTC) and Home Care (HC) settings on adult patients with chronic, acute, subacute, traumatic, dehiscent wounds, partial-thickness burns, ulcers (such as diabetic, neuropathic, pressure or venous insufficiency), flaps and grafts.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The Invia Endure NPWT System uses the same fundamental technology as the Invia Motion for most features. The Invia Endure is identical to the Invia Motion in its indications for use and contraindications. The user interface, device hardware and accessories are also identical. The main difference is that Invia Endure does not include a 60 day lifetime. In this respect the Invia Endure NPWT System functions in the same manner as the Invia Wound Therapy predicate device, which also does not have a lifetime timer. The difference in lifetime between Invia Endure and Invia Motion is implemented in the system firmware.

SUMMARY OF NON-CLINICAL TESTS:

The Invia Endure Negative Pressure Wound Therapy System complies with voluntary standards for electrical safety, electromagnetic compatibility, and safety of home use devices. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Software Validation
- Electrical safety and electromagnetic compatibility testing per IEC 60601-1 and IEC 60601-1-2 standards, respectively
- Safety testing for use in the home per IEC 60601-1-10 standard

SUMMARY OF CLINICAL TESTS:

The Invia Endure has not been the subject of clinical testing.

CONCLUSION:

The differences between the Invia Endure and its predicate devices do not introduce a new intended use and do not raise new issues of safety and effectiveness. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended.

From the results of nonclinical testing described, Medela AG concludes that the Invia Endure Negative Pressure Wound Therapy System is substantially equivalent to the legally marketed predicate device.